MICHAEL
ANDERSON

Regulatory Affairs Lead

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Dynamic Biomedical Regulatory Scientist with 9 years of experience in the diagnostics industry, focusing on regulatory compliance for in vitro diagnostic devices. Proven track record in preparing 510(k) submissions and navigating the complexities of international regulations. Experienced in working closely with clinical and manufacturing teams to ensure product safety and efficacy.

WORK EXPERIENCE

Regulatory Affairs Lead | Diagnostic Solutions Inc.   Jan 2022 – Present

- Managed the regulatory submission process for multiple in vitro diagnostic devices, achieving a high approval rate.
- Collaborated with cross-functional teams to ensure compliance with regulatory requirements.
- Conducted risk assessments and prepared mitigation strategies for product approvals.
- Maintained current knowledge of regulatory changes impacting diagnostics.
- Facilitated audits by regulatory agencies, ensuring readiness and compliance.
- Trained new staff on regulatory processes and documentation standards.

Regulatory Affairs Coordinator | In Vitro Diagnostics Corp.   Jul 2019 – Dec 2021

- Assisted in the preparation of 510(k) submissions, contributing to timely product launches.
- Reviewed labeling and promotional materials for compliance with FDA regulations.
- Maintained regulatory documentation and ensured accurate record-keeping.
- Supported the development of training programs on regulatory compliance.
- Conducted internal audits to identify areas for improvement in regulatory practices.
- Monitored regulatory updates and communicated changes to relevant teams.

SKILLS

Diagnostic regulation   510(k) submissions   Risk assessment   Compliance auditing   Cross-functional collaboration

Training

EDUCATION

Bachelor of Science in Biomedical Science   2011
University of California

ACHIEVEMENTS

- Played a key role in achieving 100% compliance during regulatory audits.
- Recognized for exceptional performance in managing regulatory submissions with zero delays.
- Developed a tracking system for submissions that reduced errors by 35%.

LANGUAGES

English   Spanish   French